

REMARKS

Claim Rejections Under 35 USC 112, second paragraph

The Office Action rejects claims 9 and 24 for reciting "essentially pure". Applicants respectfully disagree with the rejection as one of ordinary skill in the art, in view of the specification and what is known in the art, would understand what was meant. Nevertheless, to advance the application to allowance, applicants amended these claims as recommended by the Examiner, which amendments did not narrow these claims.

Claim Objections

The claims are amended as recommended by the Examiner to overcome the objections.

Claim Rejections Under 35 USC 112, first paragraph

The claims are amended to recite the order of steps of the purification.

The Office Action alleges that the claims are not enabled to their full scope because they fail to recite the buffers to be used, choice of salts, pH, pore size and flow rate.

Applicants respectfully disagree with the rejection.

It is the function of the descriptive portion of the specification and not that of the claims to set forth operable proportions and similar process parameters.

See *Ex parte Jackson*, 217 USPQ 804 (BPAI 1982).

Requiring a recitation in the claims of the specific deuterium peroxide proportions employed in the examples to insure that activity would be an unnecessary limitation. Disclosure in the *specification* sufficient to enable practice of the invention by one skilled in the art, taking into consideration obvious modifications of the reactant ratios of specific examples, is all that is required.

See *Dinh-Nguyen*, 181 USPQ 46 (CCPA 1974).

Accordingly, requiring reaction conditions such as buffers, flow rates, etc. in the claims from applicants is contrary to the cases cited above.

Each recited reaction in the claimed process may be accomplished by the use of a variety of buffers and/or conditions that one of ordinary skill in the art can determine or select without undue experimentation. The invention taught by applicants is not so limited to be restricted to the use of a single embodiment or set of embodiments around which others can easily design around.

The subject parameters can be readily determined by those skilled in the art without undue experimentation.

For example, it was known in the art what range of molecular weights and isoelectric points grass pollen allergens usually have (see, e.g., Fahibusch et al. or Bolzaccini et al., both on file). See also the bottom of page 6 of the specification which provides some of this information.

Additionally see, for example, the cited "Current Protocols" which provides guidance as to how to carry out steps *per se* of the claimed purification methods; for example: for HIC, the Protocols mention preferred buffer salt (p. 8.4.4, last para. e.g. (NH₄)SO₄; column material, e.g., (phenyl-Sepharose High Performance) (p. 8.4.2 Table 8.4.1), etc. From the expected molecular weight range (10 - 60 kDa, see above), it requires no undue experimentation for one of ordinary skill in the art to identify other useful reagents, for example, "superdex 75 prep grade" for gel filtration in Table 8.3.4 (p. 8.3.4) of the Protocols. Common buffers for cation exchange are found in Table 8.2.1 (p.8.2.3) of the Protocols, e.g., phosphate buffer at pH 7.2. Viable columns are listed in Table 8.2.3 (p. 8.2.5), e.g., Source S., etc.

Also, determining a proper flow rate for a column material in a method as claimed is within the skill level of one of ordinary skill in the art. Applicants in this regard, for example, did a google.com search for "Superdex 75 prep grade" and "flow rate" to which 15,200 hits came up. While this is not evidence from the time of filing, it can be considered indicative of how much material was out in the art on such date

Additionally, applicants provide extensive guidance in the specification as admitted by the Office Action through figures, description and examples. The main issue raised in the Office Action is that not all species of the claims are exemplified. However, the description in the specification is sufficient guidance to one of ordinary skill in art to practice the claimed invention to its full extent without necessity for undue experimentation. Limiting the claims to the specific reagents and conditions in the embodiments taught in the specification is not necessary as the invention is not so limited. Applicants' process claims recite in a step-by-step manner a series of process steps specifically with enough detail so that one of ordinary skill in the art needs no more than familiarity with routine laboratory protocol in this art to be able to practice the claimed invention to its full scope. As such, the claims are enabled.


It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is

sufficiently demonstrated to characterize a generic invention. See *Capon v. Eshhar*, 76 USPQ2d 1078 (CA FC 2005) citing *In re Angstadt*, 537 F.2d 498, 504 [190 USPQ 214] (CCPA 1976).

Reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



Csaba Henter, Reg. No. 50,908
Anthony J. Zelano, Reg. No. 27,969
Attorneys for Applicants

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Boulevard, Suite 1400
Arlington, Virginia 22201
Direct Dial: 703-812-5331
Facsimile: 703-243-6410

Filed: August 7, 2006

K:\MERCK\2000 - 2999\2386\REPLY AUG 06.DOC